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Health Canada authorizes Moderna COVID-19 vaccine

From: [Health Canada](#)

Statement

December 23, 2020

Ottawa, ON

Health Canada

Today, Health Canada authorized the second COVID-19 vaccine in Canada, manufactured by Moderna.

Health Canada received Moderna's submission on October 12, 2020, and after a thorough, independent review of the evidence, it has determined that the Moderna vaccine meets the Department's stringent safety, efficacy and quality requirements.

Today's authorization is a critical step in ensuring additional COVID-19 vaccines are available to all Canadians in all parts of the country. The different storage and handling requirements of the Moderna COVID-19 vaccine mean that it can be distributed to isolated and remote communities, including the territories.

The Department is committed to openness and transparency. As such, Health Canada is publishing a [number of documents](#) related to this decision, including a high-level summary of the evidence that we reviewed

to support the authorization of the vaccine. More detailed information will be made available in the coming weeks, including a detailed scientific summary and the full clinical trial data package.

Health Canada and the Public Health Agency of Canada will closely monitor the safety of the vaccine once it is on the market and will not hesitate to take action if any safety concerns are identified.

The terms and conditions of the Moderna vaccine authorization require the manufacturer to continue providing information to Health Canada on the safety, efficacy and quality of the vaccine to ensure the benefits of the vaccine continue to be demonstrated through market use.

To further support the safe use of the Moderna vaccine, the National Advisory Committee on Immunization (NACI) will update its recommendations on the use of COVID-19 vaccines to inform federal, provincial, and territorial immunization programs.

The vaccine is indicated for use in people 18 years of age or older. Moderna is currently conducting additional studies in children from 12 years of age and older, and this indication could be revised in the future to include children if the data from these studies support it.

The vaccine was authorized under Health Canada's Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19. This process allowed Health Canada to assess information submitted by the manufacturer as it became available during the product development process, while maintaining Canada's high standards.

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